wasn't willing to biopsy that, so we will just have to wait and see, hopefully, it is not.

Just to put them side by side, the conventional image here, and then we will run the tomosynthesis for you here. You start seeing this condensation of tissue, I mean it just makes it much easier to see these things.

[Slide.]

There is the spiculate of the first one and then the second one right there, and just in case you don't believe me, we got both of them on the biopsy. Actually, I think they are easier to see almost on the tomosynthesis than there on the specimen, which is a switch.

[Slide.]

This is another case of a patient who came with a palpable abnormality, that we just don't really see on the mammogram, we couldn't see it in the cranio-caudal view.

[Slide.]

Here, on the tomosynthesis, if you watch right where I have got it labeled, you will see the cancer--this was an invasive cancer come into view, and I am not sure what they were feeling. We looked with ultrasound, and they were close

together, but there is a second lesion, a fibroadenoma, which again shows up on tomosynthesis.

Now, we haven't looked at trying to differentiate benign from malignant at this point, but we think that we will have probably have a better shot. We have done some preliminary reader studies that, in fact, suggest--and I can't give you all the data, because we are presenting it at the RSNA--but that suggests that we see the margins, as you might imagine, of lesions much better with tomosynthesis than conventional, so we think we should be able to differentiate benign from malignant more accurately.

[Slide.]

Just a couple more cases here and then I will wind it up. This is the case of a patient who came in and had this asymmetry deep in her breast, and she didn't have it on the other side, so we were concerned. It really wasn't that dense, but invasive lobular cancer can do funny things, so we were going to biopsy this if we didn't have any other information.

[Slide.]

The problem was that we couldn't see it on

the cranio-caudal view. We did extra views, and we really had a little bit of a quandary. She agreed to have the tomosynthesis. I put this in motion, you watch up here, you will see the lesion come into view.

Then, for the radiologists in the audience, you will notice--1 don't know if you can see from the angle you are sitting up there, the panel--you will notice that there is a nice capsule around the abnormality, which we could not see on the conventional imaging.

We know exactly where this is now, because we know it was a 6-cm thick breast, and this was at millimeter 33, so not only do we know where it is 3-dimensionally, which we couldn't tell from the conventional mammography, but we also know that it is a mixed density lesion. It has got a pseudocapsule around it with fat and dense tissue, and that to a radiologist means it's a benign hamartoma.

We were able to get this patient's old mammograms from California from eight years go, much to our surprise, and this was there eight years ago, so we are comfortable in just leaving this alone. Just based on the tornosynthesis, we

would have been comfortable leaving it alone, but knowing it has been there for eight years unchanged, that confirms our suspicion.

[Slide.]

I think this is the last case. This is a patient who came in with a palpable abnormality. These are the mammograms that you take off the pile and you put down below that you are not going to get to that day, so that your associate can read them the next day.

Very dense breast tissue and just very hard to tell what is going on. Someone thought they felt something. There actually is a little architectural distortion here, and again you can sort of see it in here. Everyone is going yeah, right.

Here, just a little bit digitized representation. Something up in here maybe, hard to tell on a cranio-caudal view.

[Slide.]

Here is the tomosynthesis. As we page through, just showing the whole breast for a second here. I think you can all see the strands coming out and the lesion right here.

[Slide.]

Just make it a little bigger and side by side. It is very hard to see much on the conventional mammogram, page through. Again, with the workstation, you can go back and forth, ***so*** it is not hard to see, but here, you can see the spiculations that really aren't even--1 don't think you can see them there--much easier lesion to see.

We actually thought that there is another lesion here, and we are in the process of going through the pathology. This turned out to be an 8-mm invasive cancer with **DCIS**, and I think what we are actually seeing is DCIS as ductal extension here. We have got to confirm that with more detailed pathological review. This is just the lesion on ultrasound.

[Slide.]

Just one more case to show you some **of** the other features with tomosynthesis. Vary again, another one you put to the bottom of the pile, there is just all kinds **of** stuff going on here. There is some funny architecture right here.

[Slide.]

Here is the tomosynthesis. As we page through, you will notice that some of these are coming into very sharp detail with very sharp

margins, and these turn out to be cysts. There is another one here again as you page back and forth, very easy to see.

Then, we come into this spiculated architectural distortion. Again, in this room, with this light, it may be hard to see, but much easier to see with all the structure noise moved out of the way or cut out of the way with tomosynthesis as we page through.

[Slide.]

I will skip that.

[Slide.]

We have actually done reader studies now with tomosynthesis and the lesions are much more conspicuous with tomosynthesis. The borders of the lesions are more clearly defined. We virtually can eliminate recall for superimposed structures because there aren't any. When you are slicing through, you have eliminated everything that is in front or in back, so anything that is there is in a plane, and is not superimposed structure.

[Slide.]

The problem of where is it 3-dimensionally will go away because if you can see it in one view, you can figure out by what slice it is on where it

is 3-dimensionally. We think--we haven't proved this yet--but we think we will be able to better differentiate benign from malignant. That, to me, would be nice, but it has got to be at least as good as a needle biopsy before I would rely on it, but that may be another feature of tomosynthesis.

The issues that we have to deal with, of course, are two hours for reconstruction per study is a little bit too long, but we have already done the math, if you will, and the computer design that will allow us to reconstruct these in just a few minutes, probably one to three minutes per image, which would be like the old days of processing a mammogram, and with faster computers, we can get that down even more.

[Slide.]

The difficulty now is that instead of one to look at, the radiologist has 60 more, or 120, or whatever, you know, your slice thickness is, and we think that there are ways of dealing with that.

It is actually not that bad. You can go through these very quickly in a workstation, you know, you can go back and forth instantaneously or slow it down, whatever you want, or once you have--and this is great after lunch, we will have

people barfing in the corridors--what you can do is take these slices and put them back together as a -dimensional projection. This is what is called a maximum intensity projection. There are different ways of doing this.

This is just a patient who had actually a previous biopsy. You can see where her skin is thinned right here. It is a benign biopsy. This is just some postsurgical change from the biopsy.

But you can get an appreciation of how you could take these slices and put them together, so that the radiologist could very quickly look at this image and the computer programs are available today where you can just sit there and turn the breast as you want it.

Whether this is the way we will look at them, whether the slice is the way we look at them, I am not exactly sure, but having worked with this system now for several years, **I** am convinced that this **is** the way we are going to be doing mammographies.

If you think you had problems regulating conventional and the digital, wait until you get to tomosynthesis. **I** can imagine the issues that we are going to face in terms of quality assurance,

but there is little doubt in my mind that the sensitivity of tomosynthesis--I mean I am biased, you know that--but I think everyone who has looked it it has agreed that the sensitivity of tomosynthesis will be higher than conventional and digital mammography, and the specificity will be higher, as well.

We know we can eliminate 25 percent of the call-backs, so that right there is pretty desirable, and then the other points that I made.

Again, I appreciate your inviting me here, and I would be happy to take any questions.

DR. PISANO: Dan, do you do all the images always in the oblique projection?

DR. KOPANS: Yes. So far we have only done them in the oblique projection. Our thinking has been that one of the advantages of tomosynthesis would be that we could eliminate having to do two compressions, which in and of itself, I think women would appreciate.

So, we have really done most of our work that way. We have talked about it, maybe it would be even better doing it in two projections, and we will look at that in the future.

MS. HARVEY: Dr. Ikeda.

DR. IKEDA: How are you archiving these, and how big are the files?

DR. KOPANS: That is a good question. The files are whatever a digital mammogram is times 60. I should have pointed that out, and thanks for the question. These are done at the same spatial resolution as the General Electric detector 100 micron pixel size, so it is a very big file.

Right now we are archiving them on CD. That is a good point, but archive gets cheaper and cheaper every year, too.

DR. IKEDA: And you are displaying them on a regular GE Advantage workstation?

DR. KOPANS: We are displaying them on a 2K by 2K monitor. I have forgotten whose monitor it is. It is not GE's.

MS. HARVEY: Dr. Karellas.

DR. KARELLAS: Dr. Kopans, we have also done tomosynthesis, and we see your excitement in that area. I would like to ask you, how do you envision that we would be using tomosynthesis in a few years as the technology matures, because it is very difficult between diagnostic or there are certain groups of patients that you might say I want to go to tomosynthesis straight, bypassing the

normal mammogram?

DR. KOPANS: It is a good question, and of course, the question. In my mind, finding early cancers is the only reason to image the breast. I mean all the diagnostic imaging that we do, I think does have some benefit for patients, but the real benefit is in finding cancers early and saving lives.

As we look at tomosynthesis, we see it as the screening test. It was interesting, I thought, well, it is only going to be in the dense breast, but even lesions in fatty breasts, small lesions in fatty breasts are much more conspicuous on tomosynthesis than they are on conventional mammography.

So, I don't have a feel yet as to whether you do the fatty breast with conventional digital and you do the tomosynthesis in the dense breast. My prediction is--again, I am biased, but I think I am going to be right--is that it will become the screening mammogram.

Now, proving that is a monumental task.

MS. HARVEY: Dr. Ikeda.

DR. IKEDA: Have you been able to display side by side, left and right breasts, because

oftentimes we look for symmetry. Probably--1 don't know if the computing power is there yet--but many people are thinking about, instead of unilateral MRI's, doing bilateral studies to look for symmetry, which can be a help sometimes.

DR. KOPANS: Absolutely. We have put them up, but what we end up doing is that everyone concentrates, you see so much detail that it is kind of like you almost forget about the other breast, but that is clearly a study.

Another thing that I didn't mention that we think is going to be very valuable is that computers now, and computer-aided detection, can look for morphologic features. They look for white spots, which are calcifications. They look for certain linear projections to look for spiculation. They are not very good at looking at masses, but they can't look at last year's mammogram and see if there has been a change to this year's mammogram, you just can't do that with 2-dimensional imaging.

We think with 3-dimensional imaging, we will be able to teach computers to look for changes between last year's tomosynthesis and this year's tomosynthesis, because you have a 3D dataset that can be warped and registered, so you can see what

1 has actually changed.
2 So, we think that having 3-dimensional
3 datasets is going to open the door even further for
4 computer-assisted detection and diagnosis. I
5 hesitate to talk about diagnosis because our needle
6 biopsy techniques and even localization and surgery
7 are so accurate and safe, that you really have to
8 have a diagnostic system that was like 98 percent
9 accurate to do away or even more than that, 99
10 percent accurate to do away with biopsies.
11 But in terms of finding cancers, having a
12 3-dimensional dataset and then adding, for example,
13 contrast agents to the tomosynthesis, adding
14 ultrasound to the tomosynthesis, which we think we
15 can do in exactly the same position, so that
16 everything is perfectly registered, a lot of
17 opportunity for investigation.
18 That is why I say that, you know, digital
19 is just in its infancy, and all the different
20 things that digital is going to allow us to do are
21 what are going to make it beneficial, not just that
22 it is as good as a film-screen mammogram.
23 MS. HARVEY: Dr. Ramos.
24 DR. RAMOS-HERNANDEZ: Can you talk about
25 cost, speculated cost?

DR. **KOPANS:** It hasn't cost me a cent.

[Laughter.]

DR. **KOPANS:** Cost, again, you really don't know until the companies really get involved, and we are trying to get the companies involved. It will be more than a digital mammogram, but the real expense in digital mammography is the detector.

So, once you have the detector, what we are doing is actually, we asked for $25,000 from one of the companies to motorize the x-ray tube, we are going to do it ourselves, and they sent all kinds of people to talk to us. They must have spent well over $25,000 visiting us, didn't give us the $25,000, and then we went out and got a grant, and the company got a million dollars to do it, so they were smarter than we were.

But it is just moving the tube, that doesn't cost much. The computers are getting cheaper and cheaper and cheaper, so if a digital mammography system retails for, what, $400,000 or something, this might add $100,000 to it, but that will come down as the computers get less expensive and more systems are purchased.

We really haven't done an in-depth cost analysis because we are really in the very early

study phase of this, but I don't think it is going to add that much expense, I mean per patient, that actually doesn't, that is a few dollars per patient.

MS. HARVEY: Dr. Henderson.

DR. HENDERSON: Jessica Henderson.

Just out of curiosity, the patient who had three suspicious places--

DR. KOPANS: No, two, we don't know about the third one.

DR. HENDERSON: Why did the surgeon only biopsy two?

DR. KOPANS: Well, it gets to be tricky when you are doing research protocols, can you use the research to take care of the patient, and there are Institutional Review Board policies that start getting in the way of taking data from--I mean no one has ever done this before--so, we can't say to the surgeon, you know, we have got a track record, we know that is a cancer, and have the surgeon do a second biopsy.

So, it becomes an ethical problem. There was enough debate in the group, that no, it isn't, yes, it is, no, it isn't, that we felt it was reasonable to follow her. She has got two cancers

anyhow, she is being radiated and treated.

The issue of finding additional foci of cancer, I mean my excitement in finding those two cancers is that tomosynthesis found a cancer we didn't know about. You know, the whole issue of do you really need to know all the cancer that is in a breast, this is going to sound a little strange, but that may not be a good thing.

For example, with magnetic resonance imaging, people are finding more cancers or more foci of cancers in a breast than they originally thought, so the patient, instead of having her breast conserved, is having a mastectomy.

Yet, at least in our practice, the recurrence rates for conservation therapy are incredibly low now. Our radiation therapists just looked at their data, and it is 2 percent at eight years, which is very, very low. So, maybe those cancers that we don't find now are being killed by the radiation, and finding them may be doing a disservice to the patients.

There is a lot of issues that come up in the issue of multifocality or multicentricity in terms of cancer, so it gets, you know, when you are doing a research project, it gets even more

complicated as to how you deal with that information.

MS. HARVEY: Dr. Pisano.

DR. PISANO: Just as a follow-up to that, you probably did all the other things you would normally do with that area, right? I mean just to clarify that.

DR. KOPANS: Yes.

DR. PISANO: You probably did extra views and ultrasound and all the things, and that is why the surgeon didn't want you to go after it.

DR. KOPANS: Right.

MS. HARVEY: Dr. Karellas.

DR. KARELLAS: We often look at the cost of the procedure and the technology, but, Dr. Kopans, what do you think about the utilization or are there any potential costs to be saved if cancers are detected earlier, or of equal importance, if cancers or lesions are managed better, if you have better specificity, that way you might avoid procedures?

DR. KOPANS: I think those are all very good points. As I said, 25 percent of our recalls are for women who turn out to just have superimposed tissue, and we just have to get some

extra mammographic views to kind of look around the trees to make sure that those are just superimposed, and not an actual abnormality.

So, eliminating 25 percent of recalls is a desirable thing from a cost-benefit point of view. Then, better management of patients, those are sometimes hard to quantitate, but I think that my impression based on the work we have done so far is that our sensitivity will go up, so we will find smaller cancers, more small cancers, which I hope will translate into more lives saved. We are already seeing the decreased death rate in the United States from screening.

I think that will help us with some of the cancers that we don't find now by mammography, and certainly don't find early enough, and then having the specificity improve will reduce some of the secondary costs of screening, as you point out.

MS. HARVEY: Dr. Pisano.

DR. PISANO: I have another question. What is the time line or what is the status of this technology in terms of FDA approval?

DR. KOPANS: Oh, FDA approval. It has to be approved by the FDA?

[Laughter.]

DR. KOPANS: That will be up to the FDA, and I don't want to speak for them.

DR. PISANO: Well, it has been submitted.

DR. KOPANS: My guess would be it's at least a year for--I am being optimistic--a year for approval if we can get everything going very quickly, probably more like two years, and then approval for what is going to be the issue. Obviously, it will be approval as a diagnostic device. You can't do a screening test with it.

We will have to sit down with the FDA and figure out how we decide whether it's used for screening, because this really is different. I mean I think most people who know me, know that I think making digital mammography have to go through a PMA process was a major mistake that the FDA has done, and it is going to make it very difficult to improve the conventional digital technology.

The reason I argued against it was that , digital mammography is the same as film-screen mammography. I think D-MIST is going to show that. The other studies that have been available have shown that they are really the same.

This is different, so this is going to need a PMA and all the things that go along with

:hat. I mean I would like to see it out there in between three to five years, shorter if possible, I am not optimistic it can be shorter, but we will see.

MS. **HARVEY:** Dr. Harrison.

DR. HARRISON: This is fascinating. You nade a comment that you envision getting to a point where resolution of malignancy, if it gets up around 99 percent, we could proceed without tissue.

Do you really think we are ever going to 3et there, considering that many of the subsequent nanagement decisions are based on histologic findings?

DR. KOPANS: **No, I** think that is a good point. **I** think that histology, although there are technologies that are now looking at this, spectral analysis using lasers, we fiddled around with this a number of years ago, where you put a needle in and try and get the spectral analysis.

All of our therapy, as you point out, is based on histologic analysis and margin analysis, and that is also going to get in the way of in vivo ablation, you know, what is the margin analysis, and so on.

That is why **I** am almost discouraged that

we have to go through the diagnostic route to get technologies approved, when it is really screening that is going to be beneficial, but I understand the reasons, and they are good ones.

MS. HARVEY: Thank you.

DR. KOPANS: Thank you.

I believe we will have a break now, come back about 10 minutes after 3:00. Thank you.

[Break.]

MS. HARVEY: We are having a talk on the Inspection Demonstration Project. It's an update by Charles Gunzburg of the Division of Mammography Quality and Radiation Program.

Welcome.

Inspection Demonstration Project

DR. GUNZBURG: Thank you very much.

I am going to hopefully walk through this pretty quickly and let you know what our program is and I guess the who, what, when, and where of the program.

[Slide.]

When Congress first passed this Act, they included the requirement that there be annual inspections of all certified facilities. Initially, the compliance rate, not the

noncompliance rate, but the compliance rate was relatively low, but as soon as the facilities became aware of what we expected and became more familiar with the regulations, the compliance rate rose pretty dramatically.

Many facilities and some professional organizations were concerned, that were actually hopeful that we could inspect on a less frequent basis and actually save them some money and time.

We pointed back to the Act and said no, we can't do that, we have to do this annually.

[Slide.]

So, they went to Congress and they talked to them, and asked them to do something about it. Congress listened and when they passed the Reauthorization Act in 1998, they kept the annual requirement, but they added a provision for an inspection demonstration program, and that would be a test program under which certain facilities could be inspected less frequently than annually.

[Slide.]

It couldn't be implemented before April 2001, so that was easy. Facilities had to be substantially free of noncompliances, and the number of facilities had to be a statistically

ignificant sample of the facilities available.

They didn't specify an inspection requency, but they said that it had to be one that as capable of reasonably assuring compliance with he standards.

[Slide.1

So, FDA took that guidance and came up ith some criteria of their own, and that was that .he States and facilities would be selected ccording to a specific written criteria. We would nclude both study and control groups, and conduct nspection of the study group every two years or at Least two years on the first basis, and annual nspections of the control groups.

[Slide.1

The participation criteria for the States, Eirst of all, the State had to be willing to do it, they had to agree to do it. They couldn't have any laws or policies or requirements that meant they had to go to the facility more frequently than we were specifying in our project or our plan, and that was going to be two years again.

They had to agree to inspect at the frequency designated by **FDA.**

[Slide.1

They also had to be able to accept odifications to their contract, all these States hat have contracts with us, about how many acilities they would inspect annually, and they .ad to be able to absorb the **loss** of income from .ot inspecting these facilities, and be willing to lo that. They had to notify us if they found any roblems that were important.

[Slide.1

That left us with 14 participating groups. Ve have **11** states and **3** other testing jurisdictions.

[Slide.]

For a facility to be included, they had to iave undergone at least two inspections under the final regulations, two annual inspections. They iad to have no citations in the last two inspections under the final, and they had to have never been considered, received, or being considered for any regulatory action by FDA.

[Slide.]

They also had to anticipate providing services throughout the length of the program, and they had to maintain their accreditation and certification, and lastly, they had to be kicked

out of the program, the random selection process as being one of the facilities to be included.

[Slide.]

That left us with this. It varies between one facility in some states to 24 in Ohio, and if you lump New York together, 35 facilities in New York State.

[Slide.]

Currently, we have notified everybody that we could think of that needed to know about this program, that it was in process. We have 155 Eacilities, about 155, and approximately 155 Eacilities in the study and the control group.

Those numbers are approximate because we never know when somebody is going to drop out. So, we don't know what we are going to finally end up with, but somewhere in that region we hope.

We actually began this process in May of this year.

[Slide.]

Where are we going with it? We are going to continue the annual inspection of control groups. The changes that this necessitates means we are going to have to make some changes in the procedure and the software. We hope to have those

hanges in place by January, and we hope to have hem tested shortly thereafter, and begin testing he study group facilities about the middle of the ear.

Hopefully--this is not a real firm umber--but we hope that it works. It should inish about July of 2004 and begin data analysis t that point.

That is all I have. Questions?

MS. HARVEY: Any questions?

DR. GUNZBURG: Good. Thank you.

MS. HARVEY: Thank you.

Dr. Chakrabarti and Ms. Butler will talk to us about full field digital mammography, accreditation and certification update.

Full Field Digital Mammography

Accreditation and Certification Update

[Slide.]

DR. CHAKRABARTI: By now you have heard this several times, that GE's system was approved first by Office of Device Evaluation followed by Fischer and then Lorad, and you also know that there is no accrediting body, Dr. Finder explained that at the beginning of previous session, and we provide approval based on extending the existing

screen-film certificate.

I will briefly discuss and summarize the approval process here.

[Slide.]

Until otherwise notified by FDA, an FFDM unit will be exempt from the MQSA accreditation requirement, and until FDA issues such notification, a facility must request FDA to extend its screen-film certification to cover its FFDM units.

Requests for FFDM certification extension need to supply all the information listed in the document MQSA Facility Certification Requirements. This is on our web site, also the facility request has to provide application form, application package. There is that information about the facility certification requirements. I will give the gist of that here.

[Slide.]

In that requirement, the facility needs to furnish facility status information, FFDM Unit identification, digital image receptor identification, identification of printers for hardcopy output, monitor identification if softcopy display is available, phantom identification,

personnel qualifications.

[Slide.]

Phantom image, personnel information, Report of Mammography Equipment Evaluation, manufacturer's quality control program. I will take a brief pause and I will mention that we need, in FDA, we reviewed this with a phantom image, we need to have a phantom image.

Also, this third bullet, which says the Report of Mammography Equipment Evaluation, and that is 900.12(e)(10) of the final regulation, that is applicable to all modalities, but in case of digital, a new modality, the No. 4 bullet, which is very, very important, that means all QC programs, equipment evaluation must be performed according to the manufacturer's requirement. That is the 900.12(e)(6). That is in the final regulation.

So, when we review the Mammography Equipment Evaluation Report, we look at whether the facility has performed their tests according to the manufacturer's requirement of that FFDM system. That is very important.

Also, we need the signature of the lead interpreting physician. That signature tells us that all the information provided are true. We

don't need to have all the documentation about personnel qualifications.

We need the list of the personnel who will be working on the FFDM system, but whether that person is qualified to perform and have additional 8 hours of training, that is being sort of guaranteed by the signature when the inspector goes to the facility, inspector verifies those documentation or at the station of the personnel.

Now, once all this informations are furnished, we review the equipment evaluation report and phantom image, everything is satisfactory, we send a facility a letter of approval mentioning that your FFDM system is included with the conventional screen-film mammography certification, and that letter goes out in the name of our division director, and then the facility can perform using efficient imaging with the FFDM system.

[Slide.]

If a facility receives a letter of acceptance, the approved FFDM unit will be added to the facility's certificate.

The facility must maintain its accreditation status for at least one screen-film

.nit in order to keep its certification alive and .hen can continue to utilize FFDM unit.

The facility is also subject to an annual on-site **MQSA** inspection of its FFDM unit at the same time its screen-film units are being .nspected.

[Slide.1

The FFDM unit must be located within the same inspection jurisdiction as the certified screen-film unit. In most cases, this means that the FFDM unit must be located in the same state as the certified screen-film facility.

The lead interpreting physician must oversee the quality assurance program for both the screen-film and the off-site FFDM units. That is very important. We want to make sure that we make one person, who is the lead interpreting physician, responsible for overseeing the **QA** program in both screen-film and the FFDM system.

In general, we respond in three to five days from the time we get the application. If the application is complete, **I** showed you the gist of the information that they have to furnish, plus if the mammography equipment evaluation report is complete and perform according to the

anufacturer's requirement.

Indeed, there is the problem that we see, hat for the first time facilities and first time ıedical physicists, there is physicists having a ıumber of problems providing the proper MEE for 'FDM system.

[Slide.]

I will go over a few tests where we see :he problem. Now, here is a GE system, GE Senographe 2000D. If you look at that, you see that GE requires that signal-to-noise ratio should be over 50 in an AOP mode, standard mode and SNR check.

Now, if the facility does not, the medical physicist does not perform the test and do not use the raw image, they use process image, they get more than 100 percent inflated value of SNR. So, it does not tell us whether the SNR will pass the minimum of 50 requirement or not.

So, then, I call the physicist, they have to come back and redo the test, and this has happened a number of times.

Then, there is another one in this, that if you look at that, the GE requires the kV must not change, kV should be same if you are in the

1.5, 4, and 6 cm thickness, kV should be the target filter, and kV should not change.

There can be a range of mAs value, however, kV should be 27, 28, 32, depending on what thickness you use. We have seen in some cases, that that has changed, and we have to discuss with GE, and then that took a little more time for approval process.

[Slide.]

Another thing that I will mention in this regard is that the dose has to be performed in the AOP mode, three OF modes, and many first-time physicists haven't done that, have simply provided the dose value, but we are finding out that that is creating problem also, creating problem for us to give approval on time, which we believe we can do it within three to five days if the report is complete and tests are performed according to the manufacturer's specification.

[Slide.]

Now, these are the three tests which must be performed with raw images. Very recently I am seeing even the signal-to-noise tests are different values than what is coming forth with the raw images, because some physicists have done it with

process image.

So is MTF measurement and AOP mode and SNR check, all three tests must be performed in raw images, and it is very clear in the manual, and some physicists are missing it.

[Slide.]

I will mention here there is another reason that MTF values, some physicists have reported MTF value more than 100 percent. One way you can do that, if you do not put your elliptical region of interest tightly within the bar pattern, if it goes beyond that, then, your value would be very incited [ph], and we can look at the number, and you can see that these are not done properly.

[Slide.]

Another thing that is very important and that physicists are missing, these are the list of things that GE wants and must be performed - room layout, room description, why this is important, because if all these things are moved around, then, particularly the dark level from the monitor will change drastically and the calibration would be disrupted. So, you want to see that this information is provided properly as mentioned in the manual.

[Slide.1

Now, there is new change, there is evision of **GE's** manual is out, and **I** am seeing hat many physicists are still using the older anual. In the new manual, the physicists are not upposed to be doing any calibration, performing alibration, but they will check the calibration as erformed by the service engineer, and they will erform the records of five reference luminance evels as given by this curve.

Many physicists are missing that, they are ot giving those values or they are getting wrong lumbers.

So, these are the things that are iecessary for **GE** system to get approval within the roper time.

[Slide.1

This is the Fischer system. Here, I see that many physicists are not performing the system resolution test properly. They are using simply bar pattern and then counting the number. They must be following what the manufacturer says in their manual.

[Slide.]

Also, I see that artifacts are not far

Irom recording the window width that is specified in the manual, and this flat field tests are not performed at the region, at the corner and the :enter that the manufacturer requests.

Thirdly, the Fischer system has a contrast disc, unlike the GE system where GE prohibits use of a contrast disc with their phantom.

So, those are the things that there is a difference from one manufacturer to another nanufacturer, and even for the same manufacturer, there are changes in the manual, the physicists and the facility must be aware of that and must be performing mammography equipment evaluations and the QC according to that, and that is the cause of the delay many times.

Sometimes facilities call us as soon as they send this thing, and says we are already schedule patients, and unless they have their report properly done, we cannot give approval.

Any question or should Penny speak first?

MS. HARVEY: Any questions?

Thank you.

Sorry, Dr. Karellas has a question.

DR. KARELLAS: Kish, according to FDA, are facilities required to have a printer? I know the

use of the printer and I realize that without a printer, it is going to be very difficult to operate, but does FDA require it?

DR. CHAKRABARTI: Yes, we require for the foreseeable future, we require the original mammogram must be provided in the form of hard copy. The facility has to have a printer available for a hard copy printout when the patients ask for the original image.

DR. KARELLAS: What if the facility has an option of printing off site upon request, does the printer have to be on site, or what if the printer is within the broader institution, another Building or something like that?

DR. CHAKRABARTI: That will work out fine, but when you apply, there was a prior mention of the list, the printer, you have to mention that that printer number is this, we have to make sure that the same printer as manufacturer, is comfortable with the manufacturer's system, and if it is available off-site, then you mention it is available there, and that will work out.

MS. HARVEY: Thank you.

Ms. Butler. Good afternoon.

MS. BUTLER: Good afternoon.

I am Penny Butler from American College of Radiology, Senior Director for Breast Imaging Accreditation Programs.

I thought I would give everybody an update on where the ACR is with full field digital mammography accreditation.

[Slide.1

The last time we spoke, the full field ligital accreditation module, it is not a new accreditation program, but it is a supplement or a nodule to the mammography accreditation program that has been in place since 1987.

It was complete and it was midway through our internal ACR leadership approval. We had really hoped it was going to be out, be approved by the ACR leadership by September of 2001. I think you all know perhaps what has slowed that down.

The module that we developed was manufacturer-specific. GE was the first FDA-approved FFDM system, and the reason for this were multifaceted. First, the exposure control mechanisms are different, meaning that our instructions to facility in order to make phantom and dosimetry measurements had to be unique to the manufacturer, and due to the FDA regulations, the

required quality control is different.

[Slide.]

Since that time, in early October, ACR sent the full field digital mammography module document to the Executive Committee of our Board of Chancellors, and also at the same time, to the FDA for review.

In mid-October, these documents were approved by the Executive Committee. In nid-November, FDA had instructed us to submit a formal application for approval of the full field digital mammography accreditation module, and this formal application needed to include a number of requirements that we hadn't addressed when we sent them the documents. We weren't aware that we needed a formal application, and these were basically to address the elements that were in Part A of the regulations, similar to what we addressed in the accreditation body approval application that they approved on December 20th, 2000.

[Slide.]

At the beginning of July 2002, we submitted a complete formal full field digital mammography accreditation module application to the FDA. At the end of July, after initial review of

the application, FDA advised us that there was some of the information provided with an alternative standard request that we had submitted was insufficient.

This alternative standard request had to do with the exposure of the phantom and acquisition of dosimetry data during our mailed accreditation process.

In early August, I worked with some members of the Digital Subcommittee to collect some additional data to supplement this alternative standard request, and right now the material is under revision internally before we forward this to the FDA.

[Slide.1

So, that is the current status of the accreditation program. I would like to review some of the proposed accreditation process for full field digital mammography.

[Slide.]

In general, our process is not going to differ than what we do for film-screen mammography. The paperwork that a facility submits to us is going to depend, just like film-screen, on how much time the facility has left on their MQSA

certification and their accreditation.

In general, if they have less than **13** months left on their accreditation, all the units at the facility go through an early renewal process at the usual fee.

If they have greater than **13** months left on their accreditation, they will complete what we call a mid-cycle, we call it the New Unit Addendum Process at a reduced fee. The fee for accreditation for full field digital is not going to be any different from film-screen.

At that time, once the program is approved, the facilities will be able to have stand-alone digital systems and no screen-film will be required within the facility or associated with the facility as Kish has just described.

Keep in mind that right now, since the first application is for **GE**, right now we are talking about **GE** systems.

[Slide.]

The clinical image quality evaluation will not differ. Our Digital Subcommittee and our Committee on Clinical Image Review have determined that they **will** be evaluating the same eight attributes in exactly the same way, and that is

position and compression, exposure, contrast sharpness, noise, artifacts, and labeling.

All images will be submitted on hard copy at this time, and all of the ACR reviewers are qualified in digital mammography under the MQSA requirements.

[Slide.]

Phantom image quality evaluation is not going to differ. Again, they have to be submitted on hard copy. The scoring is going to be the same as with screen-film, that is, fibers, specks, nasses, and the subtraction of artifacts.

We have made a minor revision to how we evaluate the phantom image quality to take into consideration some of the very special artifacts that you might see for digital, but they were relatively minor, so we could just supplement our standard evaluation form.

Also, as with clinical review, the ACR reviewers are qualified in digital under MQSA.

[Slide.]

So, if all these things are the same, why do we need a separate accreditation program or a separate module to accredit digital? Well, most of this falls down to **900.12**(e)(6), as Kish had

lescribed and let me just read this to you. "For systems with image receptor modalities other than screen-film, the QA program shall be substantially ;he same as the quality assurance program recommended by the image receptor manufacturer except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film."

[Slide.]

So, we are working with the screen-film lose limit, but the QC program as specified by the nanufacturers. So, let's talk about the phantom exposure and dosimetry.

As you aware, ACR has a male dosimetry program. We tried to get radiation dose estimates concurrently with the phantom image quality, and so these are done at the same time, so we can provide better information back to the facility of what possible causes for poor image quality may be, and certainly a dose that is too low is a strong reason for why image quality may be poor.

We do this currently through a mailed TLD. The TLD dosimeter is in a little holder, it is several millimeters thick, and it is placed typically upon the phantom. With the GE system, the exposure control mechanism that is typically

used under an AOP is very different from what is used for a film screen.

The exposure control mechanism is different among the different manufacturers. Some of the manufacturers are using just strictly manual techniques right now. Consequently, our instructions to the facility have to be unit-specific, and we are very conscious about sending written instructions out to facilities because it is very easy for the technologists, who are usually the ones doing all the work, if the instructions are too technical or too physics like, it could be not clear enough. We can get some very strange numbers back.

The GE exposure is impacted by the thickest or the densest part of the breast, and if you use the routine phantom, the plastic rim around the wax block that is in that phantom, and on top of that, the TLD holder that we use, it can result is a significantly higher exposure than one would anticipate under film-screen conditions, for example, for the 4.2 cm breast.

So, we have revised our instructions for GE to have the facility first expose an acrylic block, and that acrylic block is equivalent to the

1 4.2 cm tissue, which is what the center part of the
2 ACR phantom is equivalent to under AEC to determine
3 the appropriate technique.
4 Then, we asked the facility to exposure
5 the accreditation phantom, and a dosimeter with the
6 manual technique which is closest to the technique
7 that came up under AOP mode. This is one of the
8 items that we are working with FDA on to revise, to
9 make sure that it is appropriate under the
10 regulations.
11 (Slide.)
12 In addition, we have tests listed in our
13 application materials that the facility must submit
14 either information on or a checklist showing that
15 they do these tests, and these are specific to **GE**.
16 [Slide.]
17 Likewise the medical physicist test, they
18 must submit equipment evaluat'ion and if it is an
19 annual survey, the annual survey report showing
20 that they have performed all of these tests and all
21 the tests appropriately meet the regulations.
22 [Slide.]
23 Once we receive **FDA** approval for the first
24 manufacturer's module, the **GE** module, we are going
25 to complete development of the modules for the

other FDA-approved units.

This is my last slide, but I would like to add that some of the comments that were brought up here earlier regarding harmonizing the ***QC*** test among the different manufacturers wherever possible is something that would enable us to operationally make evaluation **of** applications submitted by facilities under the accreditation program a whole lot easier, and we fully support that effort.

Any questions?

MS. HARVEY: Do we have an idea how long it will be before there is going to be an approval, like within the next six months, a lifetime? This is the question I probably get most frequently these days.

DR. FINDER: **I** would like to give you an answer. It is a process that is ongoing. Obviously, both sides here are trying to accomplish this as quickly as possible. We all understand the implications of having an accreditation body or not having an accreditation body.

I cannot give you a specific date or a time, but **I** can tell you that everybody is working as hard as they can to get this done as quickly as humanly possible.

MS. BUTLER: Obviously, FDA, the next step, well, FDA is concurrently reviewing our full application that we sent in, and we are working to provide the supplemental material to them as quickly as possible for the alternative standard.

MS. HARVEY: Thank you.

Any other questions? Dr. Gray.

DR. GRAY: Joel Gray with Lorad Corporation.

I have two questions, one for Penny and I believe one for Charlie or somebody.

You indicated that your image quality test is going to remain and the same, and the question is will the requirements for fibers, specks, and masses, 4, 3, and 3, remain the same, and the question for Charlie or someone, does this mean that each accrediting body is now going to have to go through and complete this process that ACR is, so you are going to have to go through this process of approval four more times?

MS. BUTLER: I will take the easy question. For GE, the standard was 4, 3, and 3. That is what is in their QC manual. That is what we were moving forward with.

DR. FINDER: With respect to the

ccreditation bodies, the accreditation bodies are ree to apply for FFDM. If they do, they will have o go through a process similar to what we are equiring of everybody else. It is the same rocess. So, the answer is yes.

MS. HARVEY: Ms. Martin.

MS. MARTIN: Penny and I both spent the ast couple of days going to a class on the physics of digital mammography and how to do all these wonderful tests. One comment that I got consistently from most of the attendees, and I would just pass this along, I am not sure where it will go, is that from what we could see, most of the units could do a 5-4-4 score, and we were wondering why that was not set. If the digital is capable of being better, why are we setting the score so low for the phantom image, because if you can't get a 5-4-4 out of it, you really don't have your digital set up right.

I mean why was it set so low?

MS. BUTLER: Well, we are going with the GE Quality Control Manual as far as meeting the specifications. That was outlined in that.

DR. PISANO: I know Penny knows about this, and maybe some of you also do. There is a

phantom that has been developed for D-MIST, for digital mammography, which they are calling MISTY, which is really a much more challenging phantom for digital mammography, and we are going to have a lot of data on its performance across the trial through the D-MIST, that same presentation that I referred to earlier.

I think Dan Kopans commented that really, this technology makes the ACR phantom somewhat archaic, it's not challenging enough for digital, so perhaps over time there can be a evolution to another standard or any other phantom. I like what Penny has done or what the ACR has done, it is just adopt what GE did before this phantom became available, and I think that is a reasonable first step myself.

MS. BUTLER: To expand on that a little bit more, what the subcommittee has been talking about is the current phantom the appropriate one, and I think there is a prevalent thought that there probably could be a better phantom out there, but being involved with developing new phantoms in the past and having them adopted is not something that happens overnight. You think this process is long, try to develop a phantom.

To get going, we are staying with the ACR phantom the way it is right now and then hopefully took at this in the long term.

MS. HARVEY: Dr. Karellas.

DR. KARELLAS: The issue about the various phantoms was discussed, as the ACR is well aware, with Dr. Yaffe. Dr. Yaffe is very familiar with that phantom. I believe he developed it. So, I just wanted to inform you that this decision was not totally arbitrary, and it has been decided, according to my understanding, and as Penny pointed out, that at this time, a decision was made to stay with the existing phantom.

I have no idea as to when we will be going to a new phantom. Chances are at some point, something will change.

The other issue, though, that I think is of some importance, is to consider the minimum score required for these phantoms, that we cannot make an arbitrary decision, and frankly, I cannot tell you that if we increase the score one notch, something is going to change all of a sudden.

I find often on a phantom review, that some of my objections may not be as much with scoring, Pugh scoring of all the features in the

phantom, but with the overall impression of the image, like excessive noise. Although you see everything, you just don't like the noise and the image artifacts, that they are excessive and bothersome, and I would like to see something that addresses all these issues, giving a little more latitude for the reviewers to be a little more critical.

There is latitude right now, but perhaps to the point that we can actually reject something a little more easily in the future.

MS. HARVEY: Another question?

CPT THOMAS: My name is Jerry Thomas. I am at the Uniformed Services University. Kind of a comment and a question at the same time.

It has been clearly pointed out that there are substantial differences between quality assurance programs for each of the three approved digital systems. Our current training requirements are eight hours for a new modality.

Do we have three different new modalities? I think maybe eight hours, in my experience, and I ran this program, it was this past weekend that Melissa talked about, I think maybe eight hours is not enough training.

I would suggest you may want to consider what the impact of these new modalities are going to be on both the training requirements for the technologist, as well as the medical physicist. I think probably the radiologist training could meet the eight-hour requirement without additional training, but probably not the other two.

I would like to hear other thoughts, as well.

MS. HARVEY: Ms. Martin.

MS. MARTIN: I guess my first response would be again coming from some of the other physicists, too, or their training, I think we have to look at it. I guess I don't have a problem with the eight hours of the initial training. The first time any of us have to go through one of these machines, you are going to have to go through it with the manufacturer's representative.

Certainly, eight hours of general training would not qualify you to walk in cold and do a different manufacturer's unit with absolutely no assistance, but eight hours of basic training in digital mammography imaging would qualify you to go with the engineer.

That is just an opinion, but I would agree

with Captain Thomas, you are not going to be ready to do it without anyone around.

DR. PISANO: I just have a comment about the technologists. Does anybody who is a technologist want to comment about the technologist training? Did you want to comment? I really wanted a comment from a technologist if that is possible.

MS. ELLINGSON: I am not working in the field myself, but we do have a lot of questions coming in to ASRT. They seem to think we know all the answers, but it is not very specific as to what eight hours of training is, is it applications training, is it a CE course where you heard a lecture on digital.

The questions that I am getting leads me to believe that it is not very clear what is intended for them to count as the eight hours of initial training.

MS. HARVEY: Dr. Pisano.

DR. PISANO: I just want to comment that in my experience, as I mentioned earlier, I have three different machines, and I find that the eight hours is more than adequate for the technologists to learn how to use the equipment and the tests

.hat they are required to do.

I have probably been through this process rith about, I would guesstimate 20 technologists at :his point, because we have these three units, and ve have a turnover in our place, so we have done it quite a bit. I haven't found too big of a need for additional training ever, in fact, out of all those :echs.

DR. FINDER: Going back to the question about what types of training are involved, again, ve have to go back to the history behind this. At :he time the regulations were written, these units didn't exist, *so* we tried to get the best opinions and expert advice that we could to try and settle on some type of initial training that was required, and we came up with the eight hours for the various personnel categories.

In our guidance, we have enumerated some of the things that can be used to meet this eight hours of training, and again, we were fairly flexible and general in the statement, so yes, hands-on experience can count in terms of training programs, CME courses, CEU courses would all, if they added up to the eight hours, would meet the requirement.

DR. PISANO: I think the technologists are highly motivated also to learn how to use the equipment, and if they need more time, they are not shy about saying to the equipment manufacturer representative, who is present, that they need more time learning.

I haven't found it to be a real problem. I can also say from the radiologist perspective, many radiologists have said to me--I actually run one of these programs for CME credits--and while it is a very nice way for our program to make some money, I have had many people say that they don't think eight hours is appropriate, that probably four would do, so maybe that could be shortened at some point for radiologists. It is really not that different.

The main difference is reading on softcopy, so that is just another viewpoint on that.

MS. HARVEY: Mr. Crocker.

MR. CROCKER: This is Ken Crocker from Fischer Imaging again.

I just wanted to kind of reiterate that I think we need some urgency in developing some uniformity. You know, if you look at some of the

imes lines here, GE had their PMA approval in ecember of 2000, and we are here today yet, and or one manufacturer and with one accrediting body, e don't yet have the process moved over to the ccrediting bodies.

The other thing I would like to point out s that it appears that the approach that is being aken is very linear or sequential rather than in arallel. I think as Penny mentioned, they are orking very hard to work with one accrediting ody, with one manufacturer, to get one approval.

If we continue that approach into the Euture, it is going to really tie a lot of people p and a lot of users up not having achieved their transfer over to what the regulation really intended.

That is just a comment.

MS. HARVEY: Thank you.

Another question?

MS. MARTIN: As a consulting physicist, I can only support Penny's comment and Ken Crocker's comment. If there is one set of forms, one set of measurements that we are all expected to make, that is to the benefit of all the physicists.

MR. VASTAGH: My name is Steven Vastagh.

am with the NEMA, National Electrical Ianufacturers Association. I am pleased to :ecognize that it is wonderful that we have, not)ne, but three or four different solutions for iigital mammography, so there are two sides for :ach issue, but I am pleased to tell you that NEMA ind the manufacturers will begin to make an effort :o harmonize QC tests. I am real pleased to hear :hat the accreditation bodies are supportive of :hat and hope that this will contribute to speeding ip the process.

MS. HARVEY: Thank you.

Any further questions? No? Thank you.

Let's move on now to Dr. Burkhart, who sill tell us a little bit about States as Certifiers.

States as Certification Agencies Update

DR. BURKHART: I am going to give a brief update. The way I should start is to point out that these activities all originate from Subsection Q of the original Mammography Quality Standards Act of 1992.

Subsection Q permits FDA to authorize State agencies to carry out some of the functions under our oversight. Perhaps most visible of these

functions is the actual issuance of the certificates to the facilities, the certificates that they need to be able to do mammography, and because of the visibility of this particular function, that is why we refer to the whole effort as State's certifiers or we commonly use the acronym **SAC** to refer to these activities.

But it shouldn't be forgotten that this is not the only function that the States can be authorized to carry out. Among other functions is administrative control of the inspection activities within their borders. **As** I think probably everybody knows, the great bulk of the inspections are performed by State personnel under contract to **FDA**, under general **FDA** oversight and administrative control, but a **SAC** State can have the function of that general administrative control.

With this comes any associated follow-up actions to the inspections, any follow-up on the Level 1 or Level 2 citations can become the responsibility of the **SAC** State.

To go a step further, if compliance actions are necessary, these also can be a function which the State can be authorized to carry out although I should mention in connection with that,

FDA still has the right, the authority to carry out compliance functions within a SAC State, as well as the State itself.

On the other hand, I should point out that perhaps a major function that can't be delegated to a SAC State is the function of developing the standards for the accreditation bodies or for the Facilities.

This is specifically prohibited by law being delegated to a SAC State, and we define this as including not only the regulations, but also the guidance which interprets the regulations. This remains an FDA function again the SAC States.

Before we could open up the possibility nationwide of States becoming SAC States, we needed to have implementing regulation, and to help us develop these regulations, about three years ago now, a SAC demonstration project was established, which the idea was that a limited number of States, for a limited period of time, would be given SAC functions to carry out.

They would be authorized to carry out the functions that I mentioned. So, for about three years now, the States of Iowa and Illinois have been recognized as SAC States, and they have been

carrying out the functions that I mentioned, and Erom this experience, we have gained a great deal of information which has been useful to us in developing regulations.

It has also been useful to use in our thinking about the long-term oversight activities, but now we are ready to move on to another plane because on February 6 of 2002, **SAC** regulations were published as final, and they became effective on May 7th.

So, now we have a third subpart to the **MQSA** regulations. Subpart **A** is accreditation bodies. Subpart B is the facilities. Now we have Subpart **C** for the **SAC** States.

So, as new States enter the program, they will be looked at, their applications will be looked at under these new regulations, and the maintenance of activities also will be the oversight will be directed by the new regulations.

Probably one question which may come to your mind is are there other States that are interested in becoming in **SAC** States, and several States have mentioned some interest to us. This interest is buried in inquiries in some cases, and in other cases, the States have gone further.

Probably the most time-consuming part of becoming a **SAC** State is in the development of regulations because it is required by the law that a **SAC** State have regulations in the mammography area equivalent to the **MQSA** regulations for the facilities.

On the State level, as on the national level, it takes time to develop regulations, so a State that is interested in becoming a **SAC** State, seriously interested, that is a logical first process to get started to begin developing their regulations.

It is also prudent if they are going to go this way, it is prudent for them to talk to us about their plans to begin with rather than go through the process, if the regulation is final, and then discover that they are not satisfactory and have to go through it again.

So, this is a prudent first step to discuss the regulation plans with us. There have been States that have discussed regulations that they are working on with us, have discussed with us the regulations they are working on for this purpose.

But at the present time, we have no active

applications in-house under review to produce SAC States, so at the present time, the only SAC States which exist are the two which we active under the demonstration project, the States of Iowa and Illinois are our current SAC States.

So, this brings us up to date to where we stand today. The big news again since the last time this committee met was the publication of the regulations as final. That has been the major change.

If there are any questions, I would be happy to try to answer them.

MS. HARVEY: Any questions? Dr. Pisano.

DR. PISANO: In the guidance document, what about Arkansas, California, and Texas, that are listed in the guidance document? I am a little confused maybe.

DR. BURKHART: Arkansas, California, Texas, and Iowa, I think what you are referring to as accreditation bodies. This is different from becoming a State's Certifier.

For a facility to become certified, as you know, it has to be accredited, and we can approve as accreditation bodies, we can approve States or private, nonprofit bodies, and we have the four

State AB's plus ACR, of course, as accreditation body.

But this is the next step issuing the certificates once a facility is accredited and making sure that they are inspected properly and, as I said, carrying out any compliance actions and follow-up which is necessary,

DR. PISANO: *So,* Illinois is a certifying State, but not an accrediting State.

DR. BURKHART: Right, Iowa is both. California, Texas, and Arkansas are just accreditation bodies at the present time.

MS. HARVEY: Thank you.

I think we have come to the last part of our meeting. Dr. Finder.

DR. FINDER: Just before we go and review the summary minutes, some issues again were brought up just the last few minutes, again about accreditation for FFDM, and I just wanted to clarify a few things.

One is FDA only can deal with what we get in-house. The accreditation bodies obviously have to make their own decisions whether they are going to go ahead and accredit under FFDM or not. That is their decision. We can't force anybody to do

anything.

We certainly are willing to look at any comments that an accreditation body wants to submit to us if they want ***to*** apply for FFDM. The same is true for alternative standards and some other aspects of the FFDM program. Manufacturers are certainly free to submit materials to us if they believe that they are appropriate for us.

Just to go back to one of the earlier statements in terms of approved alternative standards, one manufacturer did come in to us for an alternative standard regarding, not the frequency, but the amount of time that a unit could be still used depending on the QC test that was failed.

Other manufacturers are certainly free to apply for the same thing. That is their decision, and if they don't want to, facilities, if they want to, can also apply for an alternative standard.

We are certainly open to comments and suggestions and efforts by manufacturers and other entities with this process, we are certainly open to that, so the more, the merrier.

Review of Summary Minutes of August 2001

DR. FINDER: Next, in terms of the review

of the summary minutes, if anybody has any comments.

MS. HARVEY: Are there any corrections or additions that any members of the committee found when they reread the summary minutes of our last meeting?

[No response.]

MS. HARVEY: Very good. Excellent.

Dr. Finder, do you want to talk to us a little bit about future meetings?

DR. FINDER: Yes, but before I talk about future meetings, I do want to make mention of one fact. Dr. Amy Lee has served on our committee, and her term is expiring in January of next year, so chances are we will not be having another meeting before her term expires, so we just want to thank her for all her efforts and hope that this has been an enjoyable experience.

We know that we have gained a lot from her insights into this area, and we thank her for her participation here.

MS. HARVEY: Thank you, Dr. Lee.

Future Meetings

DR. FINDER: As for future meetings, the plan probably is going to be to have a meeting

sometime in the spring. This is going to be somewhat based on what happens. As many of you are aware, the Mammography Quality Standards Act is in the process of reauthorization. It terminates in October of 2002. Hopefully, we will have some action by Congress to reauthorize the program for another five years.

When they reauthorize it, it is not incommon--I shouldn't say uncommon--they reauthorized once and did put in specific items that required immediate attention from that reauthorization.

Depending on what is included in the reauthorization this time around, we may have to take some immediate actions to generate some new regulations depending on what they say. So, the plan is to have a meeting sometime in the spring, and the topics may be dictated by what happens in the reauthorization process.

I would expect that if they do reauthorize and put in a few new items, we might be talking about a two-day meeting rather than a one-day meeting, so just to get everybody informed.

As for the exact timing, I will try and do the same thing that I did for this meeting, which

s send out requests for days that are available rom everybody and try and generate a suitable time hat is applicable to everyone.

I will mention the fact that this was the irst time that we tried to send out all the aterials electronically. It was quite an xperience. I got a lot of e-mails that were ounced back at me and a lot of comments about it, ut I think we are going to work through that rocess and hopefully, this time around it will be moother.

For those people who got their e-mails, ut no attachments, I think it may be that your systems have recognized my name and are stripping ff the attachments immediately. I am on your spam List I guess.

MS. HARVEY: Any other further comments, pestions?

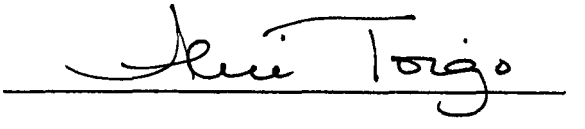
I wish you all a safe trip home and we will meet again. The meeting is closed.

[Whereupon, at 4:10 p.m., the meeting was adjourned.]

- - -

C E R T I F I C A T E

I, **ALICE TOIGO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting **by** me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.



ALICE TOIGO